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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/753,750	11/29/96	LO R	63637-6102

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EXAMINER
WEATHERSPOON, J

ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 06/11/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/753,750

Applicant(s)
Lo et al

Examiner
John K. Weatherspoon

Group Art Unit
1645



☒ Responsive to communication(s) filed on Feb 16, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 30-51 is/are pending in the application.

Of the above, claim(s) 41, 42, 45, and 48 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 30-40, 43, 44, 46, 47, and 49-51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicants' request dated 2/16/99 for a Continued Prosecution Application (CPA) (Paper No.11) under 37 CFR 1.53(d) based on parent Application No. 08/753750 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' preliminary amendment dated 2/16/99 has been entered into the record as Paper No.12. Applicants have added new claims 30-51. Although claims 30-40, 43-44, 46-47 and 49-51 are drawn to the invention of originally elected Group I, i.e. an isolated nucleic acid molecule encoding transferrin binding protein A (TbpA) protein, claims 41-42, 45 and 48 are withdrawn from further consideration as being drawn to a non-elected invention.

Priority

2. If applicant desires priority under 35 U.S.C. 119(e) based upon previously filed provisional U.S. application 60/008569, specific reference to said earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be

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incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 and dependent claims thereof, i.e. claims 31-40, 43-44, 47 and 49-51, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to the previous rejection of claims 4, 8 and 10 under 35 U.S.C. 112, second paragraph, said previous rejection is moot since applicants have cancelled said claims 4, 8 and 10. However, the examiner has rejected new claims 31-40, 43-44, 47 and 49-51 based on the same reasons as set forth the previous rejection of claims 4, 8 and 10. Applicants argue that "a

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variety of known algorithms are disclosed publically” and that a skilled artisan can recognize that any one of said algorithms can be used for conducting homology searches. Applicants arguments have been fully considered but are not persuasive for the following reasons: the term “80% identity” in said new claims is a relative term which renders the claims indefinite, and the specification (e.g. page 9) does not provide a standard for ascertaining the exact parameters of 80% sequence identity as claimed, and one skilled in the art would not be reasonably apprised of the scope of the invention. Absent both the *specific* algorithm and the parameters employed to determine percent identity of two nucleic acid sequences, the metes and bounds of the nucleic acids as instantly claimed can not be ascertained.

6. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation “a heterologous nucleic acid molecule whose nucleotide sequence is identical to the sequence of the isolated polynucleotide of claim 30” is vague and indefinite since one skilled in the art recognizes that a heterologous nucleic acid molecule by definition, i.e. heterologous defined as non-homologous or non-identical, cannot therefore also be “identical” to claimed “sequence of the isolated polynucleotide of claim 30”.

7. Claims 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitations “an isolated nucleic acid molecule encoding a homolog of any of the polynucleotide of claim 30” and “an isolated DNA molecule encoding a homolog of the

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polynucleotide of claim 30" are vague and indefinite since one skilled in the art recognizes that a nucleic acid or DNA molecule cannot "encode" a homolog of a polynucleotide, i.e. a polynucleotide cannot "encode" another polynucleotide.

8. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "an isolated DNA molecule encoding a homolog of the polynucleotide of claim 30". There is insufficient antecedent basis for this limitation in the claim since it is unclear to one skilled in the art which polynucleotide of claim 30 is referred.

9. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 recites the limitation "or a degenerate variant thereof". There is insufficient antecedent basis for this limitation in the claim since it is unclear to one skilled in the art whether said degenerate variant refers to claimed "fragment of the P.haemolytica genome", or claimed sequence "which is 5' to the open reading frame", or claimed SEQ ID NO:1.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 30-31, 33, 43-44 and 46-47 rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al (1993 reference; cited in previous Office Action). With regard to the previous rejection of claims 1-4, 8 and 10 under 35 U.S.C. 102(b) as being anticipated by Murphy et al (see previous Office Action), said previous rejection is moot since applicants have cancelled said claims 1-4, 8 and 10. However, the examiner has applied the same prior art reference to the rejection of claims 30-31, 33, 43-44 and 46-47 under 35 U.S.C. 102(b). Applicants argue that new claim 30 does not read on Murphy et al since extracting full length/intact chromosomal DNA "requires special procedures" which were not used by Murphy et al. Applicants arguments have been fully considered but are not persuasive since applicants have provided insufficient guidance for one skilled in the art to determine exactly the parameters required to employ said "special procedures". Applicants further submitted one 1996 reference and one 1997 reference that "describe the types of conditions" which must be used to extract full length/intact chromosomal DNA. Applicants references are not persuasive since they would not have been known to one skilled in the art at the time the instant application was filed, i.e. the two references submitted by applicants were published after the effective filing date of the instant application. Further, applicants arguments on pages 10-11 of applicants response provide insufficient guidance for one skilled in the art to determine exactly how the conditions for extraction of chromosomal DNA as outlined in the 1996 and 1997 references pertain specifically to the conditions as set forth by Murphy et al.

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Applicants further argue that the disclosure by Murphy et al does not read on the instantly rejected claims. Applicants arguments have been fully considered but are not persuasive for the following reasons: Murphy et al disclose isolation of total DNA from isolates of *Pasteurella haemolytica* (see entire reference, e.g Methods section and Figure 1). Since the limitations of instant claims 30-31, 33, 43-44 and 46-47 are *encompassed by* disclosure of total DNA from *Pasteurella haemolytica*, i.e. limitations drawn to an isolated polynucleotide comprising a polynucleotide having at least 80% identity to claimed polynucleotides as set forth in instant claim 30(a)-(d), further wherein claimed polynucleotide is DNA, the further claim limitation drawn to isolated fragment of *P. haemolytica* genome, and limitation drawn to "an organism which has been altered" to contain claimed polynucleotide (e.g. anticipated by prior art disclosure of isolation of total DNA from *P. haemolytica* isolates, since said isolates were "altered", wherein "altered" reads on isolation procedure), therefore all the limitations of said instant claims are anticipated by the prior art.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-31, 33, 36-39, 43-44, 46-47 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy et al (cited above) in view of Schryvers et al (1992 reference; see PTO-892), and further in view of Loosmore et al (cited in previous Office Action). The teachings of Murphy et al are set forth above. Murphy et al does not teach expression of transferrin binding protein, a vaccine comprising claimed polynucleotide set forth in instant claim 30, and expression of said polynucleotide in vivo to generate an antigenic response.

With regard to the previous rejection of claims 1-4, 8, 10, 12, 14, 20 and 28 under 35 U.S.C. 103(a) as being unpatentable over Murphy et al in view of Loosmore et al (see previous Office Action), said previous rejection is moot since applicants have cancelled said claims 1-4, 8, 10, 12, 14, 20 and 28. However, the examiner has applied the same prior art references, further in view of Schryvers et al, to the rejection of claims 30-31, 33, 36-39, 43-44, 46-47 and 49-51 under 35 U.S.C. 103(a). The examiner has addressed (see above) applicants arguments on pages 12-14 with regard to the teachings of Murphy et al. Applicants further argue that Murphy et al teach genetic differences between different serotypes of *P.haemolytica*. Applicants arguments are not persuasive since arguments are not commensurate in scope with claimed invention, i.e. the instant claims are not drawn to different serotypes of *P.haemolytica*.

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Applicants further argue that the teachings of Loosmore are drawn to a specific bacterial group, i.e. Haemophilus. However, applicants arguments are not persuasive to overcome the instant rejection since the examiner has applied the teachings of the same prior art references (i.e. Murphy and Loosmore), further in view of Schryvers et al, to the rejection of claims 30-31, 33, 36-39, 43-44, 46-47 and 49-51 under 35 U.S.C. 103(a). Further, applicants' arguments citing Maniatis et al with regard to "stringent hybridization conditions" are not persuasive since arguments are not commensurate in scope with claimed invention, i.e. the instant claims do not read on "stringent hybridization conditions". The teachings of Loosmore et al is set forth in the previous Office Action, in particular expression of transferrin binding protein and use of recombinant expression vectors expressing transferrin binding protein as vaccines (see entire reference). Loosmore et al does not teach vaccine antigens, expressed by recombinant expression vectors, comprising transferrin binding protein isolated from Pasteurella haemolytica.

Schryvers et al teach expression and isolation of transferrin binding protein from Pasteurella haemolytica, and further use of said P.haemolytica transferrin binding protein for use as vaccine antigen (see entire reference). In view of the combined teachings of Murphy et al, Loosmore et al and Schryvers et al, it would have been obvious to one of ordinary skill in the art to make and use the invention as claimed, i.e. isolated polynucleotide encoding claimed transferrin binding protein from Pasteurella haemolytica, expression of said transferrin binding protein using recombinant expression vector, vaccine comprising said polynucleotide, and methods for treatment of P.haemolytica infection comprising administering said vaccine, wherein

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said vaccine comprises claimed polynucleotide which is expressed in vivo, encoding said transferrin binding protein from Pasteurella haemolytica, to generate an antigenic response.

Status of Claims

12. No claim is allowed.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Weatherspoon, Ph.D. whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (703) 308-3995.

John Weatherspoon, Ph.D.

June 4, 1999



Anthony Caputa, Ph.D.

Supervisory Primary Examiner

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